

REMARKS

The pending Office Action addresses and rejects claims 1-8, 10-14, 16-21, 23-27, and 29-33. Claims 29-31 were previously withdrawn from consideration. Reconsideration is respectfully requested in view of the following remarks.

Rejections Pursuant to 35 U.S.C. § 103

The Examiner continues to reject claims 1-8, 10-14, 16-21, 23-27, and 32-33 pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2002/0127265 of Bowman et al. ("Bowman"), and International Patent Publication No. WO 01/85226 of Huckle et al. ("Huckle") as exemplified by Boland et. al. (*J. Macromol. Sci.-Pure Appl. Chem.*, 2001, A38(12), p 1231-1243) ("Boland"). Applicants respectfully disagree.

Claims 1 and 19 each recite that the scaffold has an initial modulus of elasticity greater than about 1.5 MPa. Bowman does not teach or suggest a scaffold having the claimed modulus of elasticity. Indeed, in a previous Office Action dated May 4, 2007, the Examiner admitted that Bowman "does not explicitly teach the specific modulus of elasticity...of the claimed scaffold." The Examiner now states that "the concern of the Examiner regarding the modulus of elasticity is directed to inherent physical properties of the composition."

The Examiner appears to rely on the lower standard required to shift the burden of proof to Applicants for product-by-process claims. See, e.g., MPEP 2113. For a product-by-process claim, the burden shifts to the Applicant to show an unobvious difference between the claimed product and the prior art product once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to the prior art. *Id.* In contrast, for composition, product, or apparatus claims, the Examiner must also provide a rationale or evidence tending to show inherency before the burden shifts to Applicants to show an unobvious difference. See MPEP 2112 IV. Claims 1 and 19 are not product-by-process claims. The correct analysis therefore proceeds as outlined in MPEP 2112, not MPEP 2113.

As such, the Examiner bears the initial burden to develop reasons supporting a reliance on inherency. MPEP 2112 (IV). To satisfy this burden, the Examiner must "provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP § 2112 (IV), citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in

original). “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *Id.*, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1057 (Fed. Cir. 1993) (emphasis in original). Thus, inherency “may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Id.*, citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Here, the Examiner argues that “[t]he absence of explicit strain requirements in [Bowman] does not obviate the examiner’s argument, where the physical property in question is testable.” However, the mere fact that a physical property is “testable” is insufficient to shift the burden of proof to Applicants. The Examiner also attempts to argue that Bowman’s disclosure of a tensile strength and a tear strength for “suitable elastomeric copolymers” provides sufficient evidence to suggest that Bowman “would likely have a modulus of elasticity greater than about 1.5MPa, based on the stress and strain requirements set forth.” The Examiner’s argument that it is “likely” that an undisclosed physical property would be present in Bowman amounts to an assertion that the claimed modulus of elasticity may be present in Bowman. The mere fact that Bowman may have the claimed modulus of elasticity is not sufficient to establish the inherency thereof. Consequently, the Examiner’s reliance on inherency is unsupported and thus improper.

Furthermore, the Examiner’s arguments imply that Bowman sets forth a strain requirement. This is incorrect. Bowman does not disclose a strain requirement. Neither tensile strength nor tear strength are a strain requirement. In the absence of a strain requirement, modulus of elasticity, i.e. the ratio of stress to *strain*, cannot be calculated. It is therefore impossible to provide any reasonable technical reasoning based on the disclosure of Bowman that to support a determination that the claimed modulus of elasticity necessarily flows from the teachings of Bowman. Finally, the disclosed values are merely properties of the elastomeric copolymers themselves. There is no teaching or suggestion that the Bowman’s polymeric foam has the same properties as the raw polymers, much less that the implant itself has the same properties. There is simply no basis in fact or technical reasoning to reasonably support the determination that the claimed modulus of elasticity necessarily flows from the teachings Bowman.

Claims 1 and 19 each also recite, in part, that the scaffold includes a “nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc.” The Examiner’s arguments regarding the obviousness of the claimed density range are unclear at best.

The Examiner previously argued that the Patent Office does not have the facilities to determine whether the scaffolds taught by [Bowman] or by [Huckle] have densities that meet the limitations of the instant claims,” citing to *In re Brown*, 459 F.2d 531 (CCPA 1972), and *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). In the pending Office Action, the Examiner merely asserts that “[t]he issue is not one of equivalency.” Thus, it appears that the Examiner is asserting that the claimed density range is an inherent physical property of Bowman’s implant. However, the Examiner has failed to make out a *prima facie* case of obviousness on the basis of inherency with regard to the claimed density range. A *prima facie* case can only be established “[w]here the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes.” MPEP 2112.01 (I).

Here, the claimed nonwoven polymeric material is not even equivalent to the materials disclosed by Bowman, much less identical. The mere fact that the density of Bowman’s mesh “is a testable physical property” does not support the contention that Bowman’s mesh is identical to the claimed nonwoven polymeric material. Indeed, Applicants disclose that “[t]he term ‘nonwoven’ as used in the present invention, and as understood by one skilled in the art, *does not include woven, knit, or mesh fabrics.*” Published Application at paragraph 0048, (emphasis added). Furthermore, Bowman discloses that a “low density, or open knitted mesh material, is preferred.” Bowman at Paragraph 0066. Thus, not only does the instant specification suggest that Bowman’s mesh is different to the claimed nonwoven polymeric material, the teachings of Bowman also tend to show that the compositions are different. Finally, Bowman also fails to teach or suggest that the mesh material has a density in the claimed range. A *prima facie* case of obviousness on the basis of inherency has therefore not been established with respect to the density range required by claims 1 and 19.

Accordingly, claims 1 and 19 distinguish over the combination of Bowman and Huckle and represent allowable subject matter. Claims 2-8, 10-14, 16-18, 20, 21, 23-27, and 32-33, which depend from claims 1 and 19, distinguish over the cited art at least because they depend from an allowable base claim.

Obviousness-Type Double Patenting Rejections

The Examiner provisionally rejects claims 1-8, 10-14, 16-27, and 32-33 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-14, 17-29, and 32 of co-pending Application No. 11/427,477. The Examiner also provisionally rejects claims 1, 7, 10-14, 19, and 34-27 on the ground of non-statutory obviousness-type double

patenting as being unpatentable over claims 1 and 8-11 of co-pending Application No. 11/856,743. The Examiner also provisionally rejects claims 1, 7, 8, 19, 24-27, 32, and 33 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7-9, 12, and 13 of co-pending Application No. 11/856,741.

Applicants believe that all pending claims are allowable. Applicants will file appropriate terminal disclaimers if so warranted. The instant application, however, was filed earlier than the applications that form the basis of the non-statutory double patenting rejections, and thus the Examiner should withdraw the provisional rejections and permit this application to issue as a patent without a terminal disclaimer (MPEP §804).

Conclusion

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

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Respectfully submitted,

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